

SAUL EWING
ARNSTEIN
& LEHR^{LLP}

Charles M. Lizza

Phone: (973) 286-6715

Fax: (973) 286-6815

clizza@saul.com

www.saul.com

November 10, 2021

VIA ECF

The Honorable Freda L. Wolfson, U.S.D.J.
Chief Judge, United States District Court
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

Re: Mitsubishi Tanabe Pharma Corporation, et al. v. Sandoz Inc., et al.
Civil Action No. 17-5319 (FLW)(DEA) (consolidated)

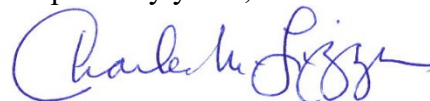
Dear Chief Judge Wolfson:

This firm, together with Paul Hastings LLP, Quinn Emanuel Urquhart & Sullivan, LLP, and White & Case LLP, represents plaintiffs Mitsubishi Tanabe Pharma Corporation, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC, and Cilag GmbH International (collectively, "Plaintiffs") in the above-captioned consolidated matter.

Further to Your Honor's September 1, 2021 Order (D.I. 258), Zydus filed a motion to terminate its appeal of this case before the Federal Circuit. The Federal Circuit issued an order granting that motion on November 9, 2021, directing that "[t]he case is remanded to the district court for modification of the final judgment orders consistent with the court's indicative ruling and this order." *Mitsubishi Tanabe Pharma Corp. v. Zydus Pharm. (USA) Inc.*, No. 21-1876 (Fed. Cir. Nov. 9, 2021). Accordingly, and consistent with the parties' Joint Motion for an Indicative Ruling (D.I. 253) and the Court's Order granting that motion (D.I. 258), enclosed for the Court's consideration is a [Proposed] Order modifying the Court's Order entered on March 22, 2021 (D.I. 244) and Final Judgment entered on April 5, 2021 (D.I. 247). If the [Proposed] Order meets with the Court's approval, we respectfully request that Your Honor sign it and have it entered on the docket.

Thank you for Your Honor's kind attention to this matter.

Respectfully yours,



Charles M. Lizza

Enclosure
cc: All counsel (via e-mail)

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700

*Attorneys for Plaintiffs
Mitsubishi Tanabe Pharma Corp., Janssen
Pharmaceuticals, Inc.,
Janssen Pharmaceutica NV,
Janssen Research and Development, LLC,
and Cilag GmbH International*

Sean R. Kelly
Katherine A. Escanlar
Geri L. Albin
SAIBER LLC
18 Columbia Turnpike, Suite 200
Florham Park, New Jersey 07932
(973) 622-3333

*Attorneys for Defendant
Zydus Pharmaceuticals (USA) Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

MITSUBISHI TANABE PHARMA
CORPORATION, *et al.*,

Plaintiffs,

v.

SANDOZ INC., *et al.*,

Defendants.

**Civil Action No. 17-5319 (FLW) (DEA)
(consolidated)**

(Filed Electronically)

[PROPOSED] ORDER

This matter having come before the Court on the joint motion of Plaintiffs Mitsubishi Tanabe Pharma Corporation (“MTPC”), Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC, and Cilag GmbH International (collectively, “Plaintiffs”) and Defendant Zydus Pharmaceuticals (USA), Inc. (“Zydus”) D.I. 253, to modify this Court’s Order entered on March 22, 2021 (D.I. 244) and the Court’s Final Judgment entered on April 5, 2021 (D.I. 247), entered following trial over Zydus’s 100 mg and 300 mg canagliflozin tablets and 50 mg/500 mg, 50 mg/1 g, 150 mg/500 mg, and 150 mg/1 g canagliflozin and metformin hydrochloride tablets, collectively referred to as Zydus’s ANDA

Products, and on remand from the United States Court of Appeals for the Federal Circuit to consider issuing an order modifying the judgment consistent with the Court's indicative ruling on the joint motion, D.I. 258, it is hereby ORDERED that the parties' joint motion is granted; and it is further ORDERED that the Order entered on March 22, 2021 (D.I. 244) and the Court's Final Judgment entered on April 5, 2021 (D.I. 247) are modified as follows:

1. It is hereby ORDERED that Judgment on Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus") counterclaims and affirmative defenses asserting invalidity of United States Patent No. 8,222,219 ("the '219 patent"), No. 7,943,788 ("the '788 patent"), and No. 8,785,403 ("the '403 patent") (collectively, "Patents-in-Suit") as relevant to Zydus's ANDA Products that are described in Zydus's Abbreviated New Drug Application Nos. 210541 and 210542 (the "Zydus ANDAs"), and in the absence of a license from Plaintiffs, is hereby entered in favor of Plaintiffs.

2. ORDERED that, for purposes of this action only, and absent a license from Plaintiffs, the manufacture, importation, use, sale, or offer for sale in the United States of the tablets described in Zydus's ANDAs would infringe claims 12 and 20 of the '788 patent, claim 22 of the '219 patent, and claim 26 of the '403 patent, and that those claims are not invalid.

3. ORDERED that Zydus and its officers, directors, employees, agents, successors, affiliates, and assigns, and all persons or entities acting in concert or participation with them, are hereby enjoined from manufacturing, using, selling, or offering for sale in the United States, or importing into the United States, the tablets described in Zydus's ANDAs until the expiration of the Patents-in-Suit, including any patent term extensions and/or patent term adjustments and during the period of any associated pediatric exclusivity, other than as authorized by Plaintiffs.

4. ORDERED that this Court shall retain jurisdiction over this action including, without limitation, over implementation of or disputes arising out of this Order.

Dated: November 10, 2021

By: s/ Charles M. Lizza
Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426

Attorneys for Plaintiffs
Mitsubishi Tanabe Pharma Corp.,
Janssen Pharmaceuticals, Inc.,
Janssen Pharmaceutica NV,
Janssen Research and Development,
LLC, and Cilag GmbH International

Of Counsel
Eric W. Dittmann
Isaac S. Ashkenazi
Dana Weir
Max H. Yusem
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166

Attorneys for Plaintiff
Mitsubishi Tanabe Pharma Corp.

Raymond N. Nimrod
Catherine T. Mattes
QUINN EMANUEL
URQUHART & SULLIVAN LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010

Colleen Tracy James
WHITE & CASE LLP
1221 Avenue of the Americas
New York, NY 10020-1095
(212) 819-8203

Attorneys for Plaintiffs

By: s/ Sean R. Kelly
Sean R. Kelly
Katherine A. Escanlar
Geri L. Albin
SAIBER LLC
18 Columbia Turnpike, Suite 200
Florham Park, New Jersey 07932

Attorneys for Defendant
Zydus Pharmaceuticals (USA) Inc.

Of Counsel
Jay R. Deshmukh
Hershy Stern
Joshua A. Whitehill
Jayita Guhaniyogi, Ph.D.
KASOWITZ BENSON TORRES LLP
1633 Broadway
New York, New York 10019

Attorneys for Defendant
Zydus Pharmaceuticals (USA) Inc.

*Janssen Pharmaceuticals, Inc.,
Janssen Pharmaceutica NV,
Janssen Research and Development,
LLC, and Cilag GmbH International*

IT IS SO ORDERED, this _____ day of _____, 2021.

Hon. Freda L. Wolfson
U.S. Chief District Judge